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(71) Applicant: VIDACARE CORPORATION [US/US];
722 'A' Isom Road, San Antonio, TX 78216 (US).

(72) Inventor: MILLER, Larry, J.; 16260 Highway 46,
Spring Branch, TX 78070 (US).

(74) Agent: FELGER, Thomas, R.; Baker Botts L.L.P., 1500
San Jacinto Center, 98 San Jacinto Blvd., Austin, TX
78701-4039 (US).

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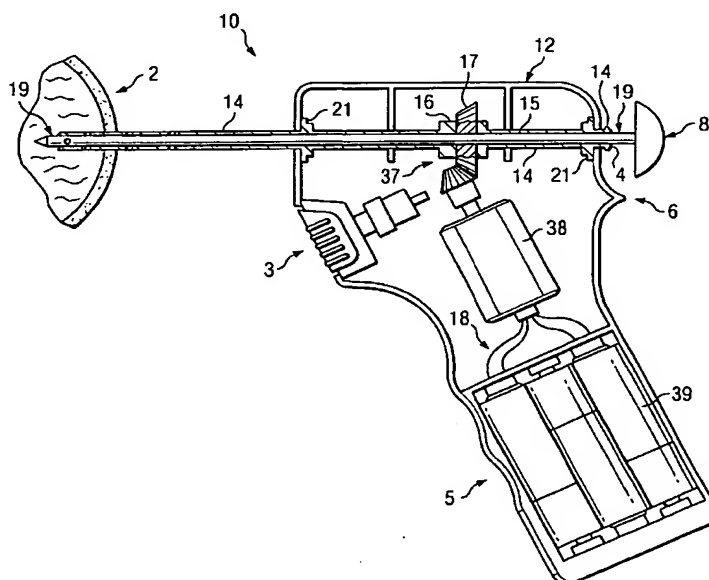
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(54) Title: APPARATUS AND METHOD TO ACCESS THE BONE MARROW



(57) Abstract: An apparatus for removing portions of bone marrow from a bone is provided. The apparatus includes a housing and a hollow drive shaft operable to engage a gear assembly. The hollow drive shaft includes a first end operable to penetrate the bone and a second end operable to allow retrieval of portions of bone and bone marrow. The apparatus also includes a removable trocar. The removable trocar includes an inner channel operable to convey portions of bone and bone marrow. The gear assembly is able to engage and rotate the hollow drive shaft. A motor operable to drive the hollow drive shaft into the bone marrow by rotation of the hollow drive shaft and a power supply and associated circuitry operable to power the motor are also included.

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APPARATUS AND METHOD TO ACCESS THE BONE MARROW

TECHNICAL FIELD

The present invention is related to an apparatus and method for withdrawing specimens from the bone or bone marrow. The apparatus and method can be used to extract
5 stem cells or bone marrow for transplantation or diagnostic purposes.

BACKGROUND OF THE INVENTION

There are many clinical conditions where it is important to be able to access and retrieve bone marrow.
10 In some cases it may be necessary to treat diseases with a bone marrow or stem cell transplant to restore functioning blood cells in the body after high-dose chemotherapy. Such conditions may include acute leukemias, brain tumors, breast cancer, Hodgkin's
15 disease, multiple myeloma, neuroblastoma, non-Hodgkin's lymphomas, ovarian cancer, sarcoma and testicular cancer. In other cases it is necessary to access the bone marrow to obtain a sample of the marrow for diagnostic testing. These conditions may include cancer of any type and
20 hematologic disease of any origin.

Current techniques for gaining access to bone marrow can be difficult, traumatic and occasionally dangerous, depending on the site selected for harvest, the operator's expertise and the patient's anatomy. In
25 general, the devices available for gaining access to the medullary cavity of the bone, where the bone marrow is located, include a trocar-fitted needle, with handles to facilitate application of pressure and rotation. These types of devices require substantial force to break

through the outer cortex of the bone by a fracturing technique. The exertion of high pressure upon the needle causes pain for the patient and often damages the tip of the needle. This is particularly a problem when

5 harvesting from the sternum of a patient because the excess force can cause penetration through the sternum and can damage underlying structures such as the heart and great vessels.

Another disadvantage of current techniques to access
10 the bone marrow is that frequently more than one penetration site into the bone is required to retrieve enough bone marrow to either perform diagnostic tests or for transplantation purposes. To retrieve an adequate sample of bone marrow for either a bone marrow or stem
15 cell transplant, a physician may need to put the needle into several different parts of the pelvis which may require up to six needle puncture sites or more. This multiple-pass requirement can be extremely painful for a patient and may deter people from donating bone marrow.
20 This technique of using multiple passes can also cause fatigue in smaller operators who may lack strength to complete multiple-pass procedures.

Retrieving bone samples for diagnostic purposes is likewise difficult. Occasionally the core sample of bone
25 is not retrieved because it is not extracted successfully with a standard biopsy needle. Thus, multiple attempts may be necessary to obtain a satisfactory bone or bone marrow biopsy.

Current techniques require that biopsy needles be
30 forced by manual pressure into bone. These techniques may have undesirable side effects such as damaging a

needle tip or having the needle slide off the proposed bone target and into organs or soft tissues.

SUMMARY OF THE INVENTION

There is a need for an apparatus and method to
5 access the bone marrow that is minimally traumatic to the patient and that allows a sufficient amount of bone marrow to be removed the first time the bone is penetrated. In accordance with teachings of the present invention, an apparatus and method for the removal of
10 portions of bone marrow from a bone are provided.

In one embodiment the apparatus includes a housing and a hollow drive shaft operable to engage a gear assembly. The hollow drive shaft includes a first end operable to penetrate the bone and a second end operable
15 to allow retrieval of portions of bone and bone marrow. The hollow drive shaft also includes an inner channel operable to convey portions of bone and bone marrow. The apparatus also includes a removable trocar with a first end operable to penetrate the bone and a second end. The
20 removable trocar includes an inner channel operable to convey portions of bone and bone marrow. The gear assembly is able to engage and rotate the hollow drive shaft. A motor operable to engage the gear assembly and drive the hollow drive shaft into the bone marrow by
25 rotation of the hollow drive shaft and a power supply and associated circuitry operable to power the motor are also included.

In another embodiment, an apparatus for removing portions of bone and bone marrow from a bone for
30 diagnostic or therapeutic purposes is provided that includes a housing and a hollow drive shaft operable to engage a gear assembly. The hollow drive shaft includes

a first end operable to attach to a penetrator and a second end operable to allow retrieval of portions of bone marrow. The hollow drive shaft also includes an inner channel operable to convey portions of bone marrow to an operator. The detachable penetrator is able to penetrate the bone marrow and collect specimens of bone marrow. Also included is a trocar having a first end operable to penetrate the bone marrow and a second end. The trocar can be removably inserted into the inner channel of the hollow drive shaft. A connector operable to releasably attach the penetrator to a hollow drive shaft is also included. A gear assembly operable to engage and rotate the hollow drive shaft is provided. A motor operable to engage the reduction gear assembly and drive the penetrator into the bone marrow by rotation of the hollow drive shaft and a power supply and associated circuitry operable to power the motor are also provided.

In a further embodiment of the invention a hollow drive shaft assembly operable to remove bone or tissue from a bone marrow is provided. An outer hollow drive shaft and a removable inner trocar operable to penetrate the bone marrow are included. The outer hollow drive shaft is removably coupled to a gear assembly and the outer hollow drive shaft includes an inner channel operable to convey portions of bone and bone marrow.

In a further embodiment of the invention a method for performing a bone marrow biopsy is provided that includes inserting a hollow drive shaft and trocar into the bone marrow by means of a powered apparatus. The trocar may be removed from the hollow drive shaft and suction may be applied to an inner channel of the hollow drive shaft so that portions of bone and bone marrow may

be retrieved from the inner channel of the hollow drive shaft.

An alternative method of performing a bone marrow biopsy is provided that includes attaching a penetrator to a hollow drive shaft and inserting an inner trocar into the hollow drive shaft and penetrator. The penetrator is then inserted into the bone marrow by a powered apparatus. The inner trocar is removed from the hollow drive shaft and penetrator, and suction may be applied to the inner channel of the hollow drive shaft to retrieve portions of bone marrow. In a particular embodiment of the invention the site of bone marrow biopsy is controlled by a second end of the trocar comprising a ratcheted gear operable to control the depth of sampling from the bone marrow.

In a further embodiment of the invention, a method of harvesting bone marrow for transplantation is provided that includes inserting a hollow drive shaft and inner trocar into the bone marrow by means of a powered apparatus coupled with the hollow drive shaft. The inner trocar is removed from the hollow drive shaft. A suction is then applied to the inner channel of the hollow drive shaft to retrieve portions of bone marrow. The inner trocar may be replaced into the hollow drive shaft. The steps of removing the inner trocar from the hollow drive shaft and applying suction to the inner channel of the hollow drive shaft to retrieve portions of bone marrow may be repeated until a sufficient quantity of bone marrow has been harvested for bone marrow transplantation.

In a particular embodiment of the invention, the site of harvest within the bone marrow may be changed by

a ratcheted gear attached to the second end of the trocar. The gear may be used to change the depth of sampling from the bone marrow.

BRIEF DESCRIPTION OF THE DRAWINGS

5 A more complete and thorough understanding of the present embodiments and advantages thereof may be acquired by referring to the following description taken in conjunction with the accompanying drawings, in which like reference numbers indicate like features, and
10 wherein:

FIGURE 1A illustrates an embodiment of an apparatus for removing a bone marrow sample shown in longitudinal cross section.

15 FIGURE 1B illustrates an embodiment of a hollow drive shaft of the current invention.

FIGURE 1C illustrates an embodiment of a trocar of the current invention.

FIGURE 1D illustrates an embodiment of an apparatus of the current invention.

20 FIGURE 1E illustrates an embodiment of an apparatus for removing a bone marrow sample shown in longitudinal cross section.

FIGURE 2A illustrates an example of a hollow drive shaft or penetrator of the current invention.

25 FIGURE 2B illustrates an example of a hollow drive shaft or penetrator of the current invention.

FIGURE 2C illustrates an example of an inner trocar of the current invention.

30 FIGURE 2D illustrates an example of a hollow drive shaft or penetrator of the current invention.

FIGURE 3A illustrates an example of an attachment of the current invention.

FIGURE 3B is an illustration of an attachment of the current invention.

FIGURE 4A is an illustration of a hollow drive shaft and trocar of the current invention.

5 FIGURE 4B is an illustration of a hollow drive shaft and trocar of the current invention.

FIGURE 4C is an illustration of a hollow drive shaft and trocar of the current invention in cross section.

10 FIGURE 4D is an illustration of a hollow drive shaft and trocar of the current invention in cross section.

FIGURE 5A-C illustrates example gear assemblies of the current invention.

DETAILED DESCRIPTION OF THE INVENTION

Preferred embodiments of the invention and its
15 advantages are best understood by reference to FIGURES 1A-5C herein like numbers refer to same and like parts.

FIGURE 1A, illustrates an example of an apparatus for removing bone marrow from a bone. Apparatus 10 may be used to obtain a sample of bone marrow from any
20 suitable bone in the body such as the iliac crest or the sternum. In one embodiment, apparatus 10 includes housing 12, a hollow drive shaft 14, removable trocar 19, gear assembly 37, motor 38 and power supply 39. Housing 12 may include on/off switch 3 handle 5 and guard 6.
25 Handle 5 may be angled downward to allow ease of operation and also to allow end of hollow drive shaft 14 to turn without obstruction from a hand. Housing 12 encompasses power source 39, motor 38 and associated circuitry 18, hollow drive shaft 14 and gear assembly 37.
30 Hollow drive shaft 14 includes inner channel 15 and collar 16. Gear 17 of gear assembly 37 engages collar 16

of hollow drill shaft 14 and thereby rotates hollow drive shaft 14.

Removable trocar 19 may be inserted into inner channel 15 of hollow drive shaft 14. Trocar 19 is hollow and has an inner channel operable to convey bone and bone marrow samples. Trocar 19 may have a handle 8 that can be used to tighten trocar 19 in place or to remove it from inner channel 15 of hollow drive shaft 14. Hollow drive shaft 14 may include luer lock connector 4 at the point where it exits housing 12. A luer lock connector may allow hollow drive shaft to connect to a suction apparatus such as a tubing or syringe or to any other suitable apparatus that would assist in obtaining a bone or bone marrow biopsy specimen. An access port, such as a suction port may also releasably attach to an end of hollow drive shaft where it exits housing 12, for example to a luer lock connector. Such an attachment may be a plug, a port, a suction apparatus, swivel port or other adapter.

FIGURE 1B shows hollow drive shaft 14 removed from apparatus 10. In one embodiment, hollow drive shaft 14 may include one or more thrust bearings 21. Thrust bearings may absorb pressure from the thrust of a drive shaft into bone during drilling. Also included in hollow drive shaft are side ports shown in further detail in FIGURE 2. FIGURE 1C illustrates removable trocar 19 which includes handle 8. Handle 8 may be formed into a shape that is easily grasped and turned during the process of obtaining a biopsy. Removable trocar 19 may include one or more side ports operable to access a bone marrow specimen shown in greater detail in FIGURE 2.

In one embodiment, shown in FIGURE 1D, housing 12 may include a releasable hatch or door 12a that may be opened to allow hollow drive shaft and attached gear 17 to be removed after use of apparatus 10. This may be desirable where apparatus 10 is reusable and hollow drill shaft 14 and removable trocar 19 are disposable. A releasable hatch or door may also be desirable to clean the inside of apparatus 10.

In another embodiment of the current invention, shown in FIGURE 1E, detachable penetrator 20 may be attached to hollow drive shaft 14 by means of connector 36 and drilled into bone 2. In this embodiment, removable trocar 19 may be inserted into inner channel 15 of hollow drive shaft 14 and into the hollow channel of penetrator 20. Penetrator 20 may include side ports to permit access to bone and bone marrow samples during a biopsy or bone marrow harvest procedure. One advantage of an embodiment that includes a detachable penetrator is it allows penetrators of various sizes and configurations to be attached to hollow drive shaft 14. In this embodiment, connector 36 includes an inner channel operable to allow retrieval of bone and bone marrow specimens.

FIGURES 2A-D show an end 22 of either a hollow drive shaft or a penetrator that is suitable to penetrate a bone. FIGURE 2A, illustrates hollow drive shaft or penetrator end 22 which may include multiple sampling ports 23 through which bone marrow or other biopsy material may be aspirated. Sampling ports 23a, 23b and 23c are each operable to retrieve a portion of bone marrow. When removable trocar end 24 is in position within inner channel of hollow drive shaft end 22

sampling port 13 of removable trocar end 24 may align with sampling port 23a, 23b, or 23c. An operator may determine the level in the bone marrow where a specimen is taken or which sampling port (23a, 23b or 23c) to align with trocar sampling port 13. Hollow drive shaft or penetrator end 22 may include serrated tip 25 as shown in FIGURE 2B or any other suitable configuration for sampling bone or bone marrow.

FIGURE 2C shows removable trocar end 24 having a sampling port 23 near tip 27 through which a sample of bone or bone marrow can be retrieved as well as through a sampling port 23a, 23b or 23c. When sampling port 23a, 23b or 23c of hollow drive shaft or penetrator 22 is aligned with sampling port 13 of removable trocar 24, a portion of bone marrow may be suctioned out of the bone. Removable trocar 24 may be removed allowing bone marrow to be suctioned through one or more sampling ports 23 of hollow drive shaft or penetrator 22 at different sites in a bone marrow cavity sequentially. FIGURE 2D shows another example of tip 25 of hollow drive shaft or penetrator end 22 having internal threads 26 that are able to engage a specimen of bone and core it out as hollow drive shaft or penetrator 22 is drilled into bone. Threads 26 may engage and adhere to a portion of bone or to a semisolid substance such as bone marrow and maintain contact with the specimen so it may be successfully retrieved.

FIGURE 3A shows operating mechanism 32 that may be included in some embodiments of the invention and may be attached to hollow drive shaft 14 and manipulated to change the depth in a bone marrow where sampling occurs. Operating mechanism 32 includes handle 35 and gear 33.

Gear 33 engages gear 34 attached to trocar 19. Suction port 28, shown attached to trocar 19, may be used to retrieve portions of bone marrow from inner channel 15 of hollow drive shaft 14.

5 FIGURE 3B shows an example suction port 28 that may be connected to trocar 19 where it exits housing 12. In one embodiment of the invention a suction port or suction swivel apparatus may also be connected to the hollow drive shaft 14. This feature allows a suction apparatus
10 of the type well known to one skilled in the art to be used to obtain bone marrow samples. Suction port 28 may also be configured to attach directly to a penetrator for example in an embodiment of the invention where the penetrator is detached from the housing before it is
15 accessed for bone marrow retrieval. Also shown in FIGURE 3B is a suction swivel apparatus 45 that allows a suction tube 41 to attach to suction port 28. Suction swivel apparatus 45 allows suction port 28 to remain attached to suction tube 41 while an attached drilling apparatus is
20 drilling into bone marrow without kinking or twisting suction tube 41. Also shown in FIGURE 3B is receptacle 43 that is interposed between suction tube 41 and a source of suction such that a bone marrow specimen may be successfully retrieved into receptacle 43 and not lost
25 into a suction machine.

FIGURE 4A-D shows an example hollow drive shaft end or penetrator end 44 and inner trocar 42 having a split-needle configuration. An inner trocar 42 is inserted into a hollow drive shaft or penetrator end 44. Inner
30 trocar 42 shown in the open position in FIGURE 4A is advanced past the end of hollow drive shaft end or penetrator end 44 where it may be opened and inserted

into bone, bone marrow or other tissue. Inner trocar 42 may be closed, shown in FIGURE 4B, so that a specimen is retained in its grasp as it is withdrawn from the body. FIGURE 4C shows a cross section of the split-needle inner
5 trocar 42 where the tip of the inner trocar 42 is in the open position. FIGURE 4D shows a cross section of the trocar 42 is shown in the closed position.

The apparatus may or may not include a reduction gear assembly. A reduction gear assembly may include a
10 worm gear assembly shown in more detail in FIGURE 5A and may include first connector 50 that connects shaft 52 of motor 38 to worm gear 54. A reduction gear assembly may be used to decrease the RPMs between the motor and penetrator assembly to provide an optimum RPM at the
15 point of insertion of penetrator assembly into bone. FIGURE 5B illustrates a further embodiment of a reduction gear assembly wherein a first spur gear 57 engages a second spur gear 58. FIGURE 5C illustrates an alternate embodiment of a reduction gear assembly wherein spur gear
20 56 is offset forty-five degrees relative to hollow drive shaft 14 which may be preferable in some embodiments of the present invention. In this embodiment spur gear 58 may be offset at any angle and is not limited to forty-five degrees. Other gears may be used in a reduction
25 gear assembly, for example a planetary gear (not expressly shown) may be used alone or in combination with a worm gear or a spur gear.

Although the present invention and its advantages have been described in detail, it should be understood
30 that various changes, substitutions and alternations can be made herein without departing from the spirit and

scope of the invention as defined by the following claims.

WHAT IS CLAIMED IS:

1. An apparatus for removing portions of bone and bone marrow from a bone for diagnostic or therapeutic purposes comprising:

5 a housing;

a hollow drive shaft operable to engage a gear assembly;

the hollow drive shaft comprising a first end operable to penetrate the bone and a second end operable to allow retrieval of portions of bone and bone marrow;

10 the hollow drive shaft further comprising an inner channel operable to convey portions of bone and bone marrow;

a removable trocar comprising a first end operable to penetrate the bone and a second end;

15 the removable trocar further comprising an inner channel operable to convey portions of bone and bone marrow;

the gear assembly operable to engage the hollow drive shaft;

20 a motor, coupled to the hollow drive shaft, operable to drive the penetrator into the bone marrow by rotation of the hollow drive shaft; and

a power supply and associated circuitry operable to power the motor.

2. The apparatus of Claim 1 wherein the hollow drive shaft and removable trocar are disposable and operable to be removed from the apparatus through a releasably coupled access panel in the housing.

30

3. The apparatus of Claim 1 wherein the hollow drive shaft is operable to attach to an access port.

4. The apparatus of Claim 1 wherein the hollow drive shaft is operable to attach to a suction port.

5. The apparatus of Claim 1 wherein the second end of the trocar is coupled to a ratcheted gear the gear operable to align the sampling ports of the trocar with the sampling ports of the hollow drive shaft.

6. The apparatus of Claim 1 wherein the removable trocar comprises a tip having a longitudinal groove operable to release bone chips from an insertion site into the bone marrow and the outer penetrator includes a cutting edge.

7. The apparatus of Claim 1 wherein the housing comprises a portion of a base mounted on a surface.

8. The apparatus of Claim 1 wherein the hollow drive shaft comprises a tip having internal threads operable to engage a bone or bone marrow biopsy specimen as it is removed from the bone marrow.

9. The apparatus of Claim 1 wherein the removable trocar comprises a tip having two separate longitudinal pieces that can move together or apart.

10. The apparatus of Claim 1 further comprising a reduction gear assembly operable to rotate the hollow drive shaft.

11. The apparatus of Claim 1 wherein the hollow drive shaft comprises at least one thrust bearing.

5 12. The apparatus of Claim 1 wherein the hollow drive shaft comprises at least one side port operable to access a portion of bone or bone marrow.

10 13. The apparatus of Claim 1 wherein the removable trocar comprises at least one side port operable to align with a side port of the hollow drive shaft to access a portion of bone or bone marrow.

15 14. The apparatus of Claim 1 wherein the hollow drive shaft comprises a luer lock connector.

20 15. The apparatus of Claim 1 wherein the inner trocar comprises two longitudinal bodies, the longitudinal bodies having tips with jaws operable to grasp a portion of bone or bone marrow and wherein the longitudinal bodies are operable to separate or come together depending on their position relative to the hollow drive shaft.

16. An apparatus for removing portions of bone and bone marrow from a bone for diagnostic or therapeutic purposes comprising:

a housing;

5 a hollow drive shaft disposed in the housing;

the hollow drive shaft operable to engage a gear assembly;

the hollow drive shaft comprising a first end operable to attach to a penetrator and a second end

10 operable to allow retrieval of portions of bone marrow;

the hollow drive shaft further comprising an inner channel operable to convey portions of bone marrow to an operator;

a detachable penetrator operable to penetrate the bone marrow and collect specimens of bone marrow;

15 a trocar having a first end operable to penetrate the bone marrow and a second end;

the trocar operable to removably insert into the inner channel of the hollow drive shaft;

20 a connector operable to releasably attach the penetrator to the hollow drive shaft;

a gear assembly operable to rotate the hollow drive shaft;

a motor coupled to the hollow drive shaft operable to drive the penetrator into the bone marrow by rotation of the hollow drive shaft; and

a power supply and associated circuitry operable to power the motor.

17. The apparatus of Claim 16 wherein the trocar comprises a tip having a longitudinal groove operable to release bone chips from an insertion site into the bone marrow.

18. The apparatus of Claim 16 wherein the second end of the hollow drive shaft comprises an access port operable to be used to obtain portions of bone and bone marrow from the inner channel.

19. The apparatus of Claim 16 wherein the second end of the hollow drive shaft comprises a suction port to remove portions of bone and bone marrow into a receptacle.

20. The apparatus of Claim 16 wherein the second end of the trocar comprises a ratcheted gear operable to control the depth of sampling from the bone marrow.

21. The apparatus of Claim 16 wherein the penetrator comprises internal threads operable to engage bone or bone marrow as the penetrator is drilled into the bone.

22. The apparatus of Claim 16 wherein the penetrator comprises two separate longitudinal pieces that can move together to grasp a biopsy specimen.

23. The apparatus of Claim 16 further comprising a reduction gear assembly operable to rotate the hollow drive shaft.

24. The apparatus of Claim 16 wherein the hollow drive shaft comprises at least one thrust bearing.

25. The apparatus of Claim 16 wherein the
5 penetrator comprises at least one side port.

26. The apparatus of Claim 16 wherein the removable trocar comprises at least one side port operable to align with a side port of the penetrator.

10

27. The apparatus of Claim 16 wherein the hollow drive shaft comprises a luer lock connector.

28. A hollow drive shaft assembly operable to
15 remove bone or bone marrow from a bone for diagnostic or therapeutic purposes comprising:

an outer hollow drive shaft, and a removable inner trocar operable to penetrate the bone marrow;

the outer hollow drive shaft removably coupled to a
20 gear assembly; and

the outer hollow drive shaft further comprising an inner channel operable to convey portions of bone and bone marrow.

25 29. The hollow drive shaft assembly of Claim 28 wherein the hollow drive shaft comprises a tip with serrated teeth, the hollow drive shaft further comprising internal threads operable to engage a portion of bone or bone marrow.

30. The hollow drive shaft assembly of Claim 28 wherein the hollow drive shaft comprises a body with at least one side port operable to obtain portions of bone marrow.

5

31. The hollow drive shaft assembly of Claim 28 wherein the inner trocar comprises a tip with a cutting edge and further comprises a body with at least one side port operable to obtain bone marrow tissue from the bone marrow.

10

32. The hollow drive shaft assembly of Claim 28 wherein the inner trocar comprises:

two longitudinal bodies, the longitudinal bodies further comprising tips with curved jaws; and

15

the longitudinal bodies operable to separate or come together depending on their position relative to the outer penetrator, and further operable to grasp a portion of bone or bone marrow between the curved jaws.

20

33. A method for performing a bone marrow biopsy comprising:

inserting a hollow drive shaft and trocar into the bone marrow using a powered apparatus;

removing the inner trocar from an outer penetrator;

25

applying suction to an inner channel; and

retrieving portions of bone marrow from the inner channel of the hollow drive shaft.

30

34. The method of Claim 33 further comprising limiting sampling of the trocar from the bone marrow by adjusting a ratchet gear coupled to the trocar.

35. A method of performing a bone marrow biopsy comprising:

attaching a penetrator to a hollow drive shaft;

5 inserting an inner trocar into the hollow drive shaft and penetrator;

inserting the penetrator into the bone marrow by rotating the drive shaft using an electric motor;

removing an inner trocar from the hollow drive shaft and penetrator;

10 applying suction to an inner channel of the hollow drive shaft; and

retrieving portions of bone marrow from the inner channel.

15 36. The method of Claim 35 further comprising selecting portions of the bone marrow for removal by limiting longitudinal movement of the trocar.

37. A method of harvesting bone marrow for transplantation comprising:

inserting a hollow drive shaft and inner trocar into the bone marrow by means of a powered apparatus coupled
5 with the hollow drive shaft;

removing the inner trocar from the hollow drive shaft and penetrator;

applying suction to the inner channel of the hollow drive shaft and retrieving portions of bone and
10 bone marrow;

replacing the inner trocar into the hollow drive shaft and penetrator;

changing the site of harvest within the bone marrow by using a ratcheted gear attached to a second end
15 of the trocar, the gear operable to change the depth of sampling from the bone marrow; and

repeating the steps of removing the inner trocar from the hollow drive shaft and applying suction to the inner channel of the hollow drive shaft to retrieve
20 portions of bone marrow until a sufficient quantity of bone marrow has been harvested for bone marrow transplantation.

1/6

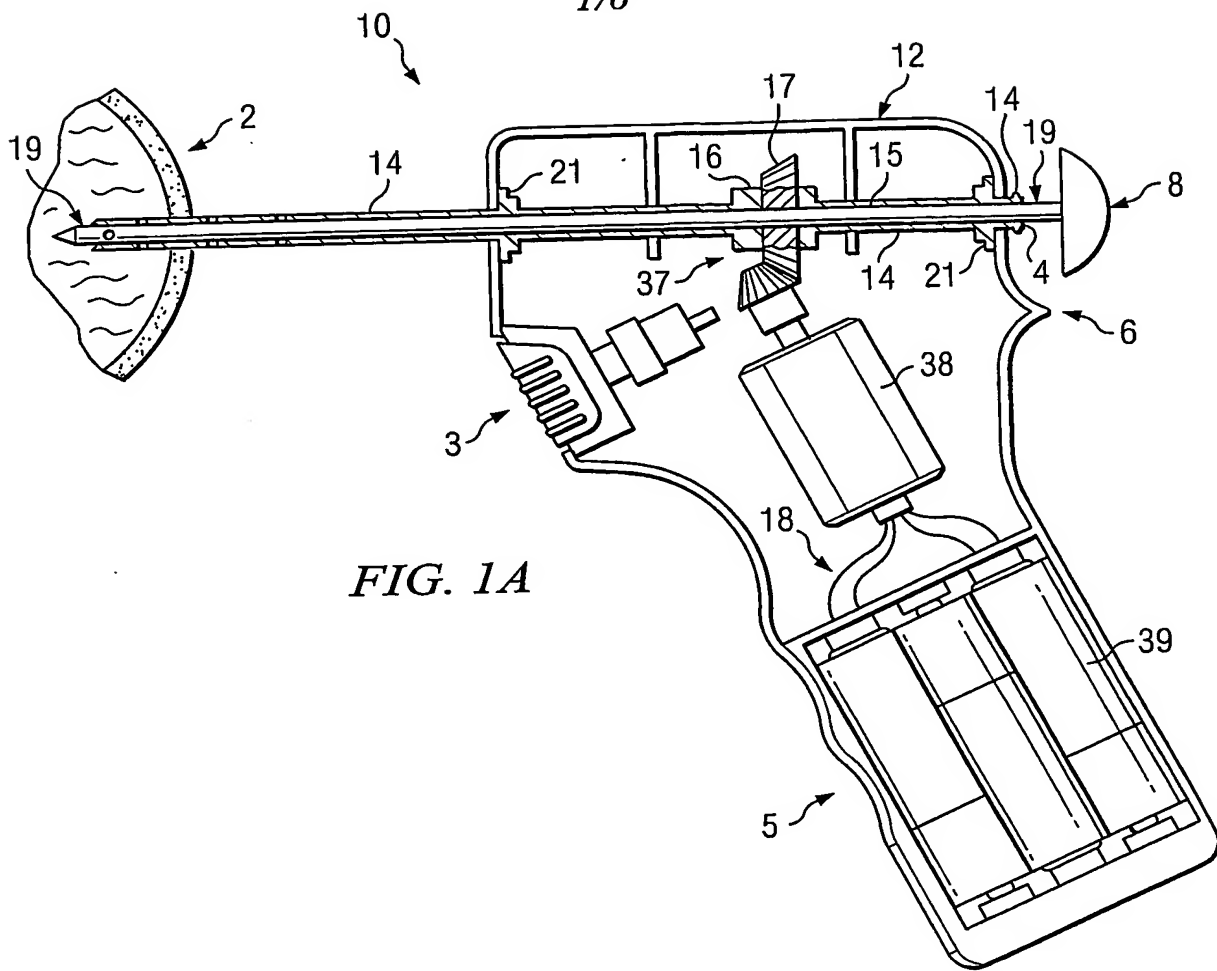


FIG. 1A

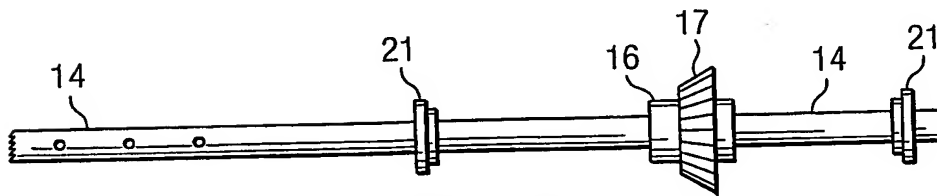


FIG. 1B

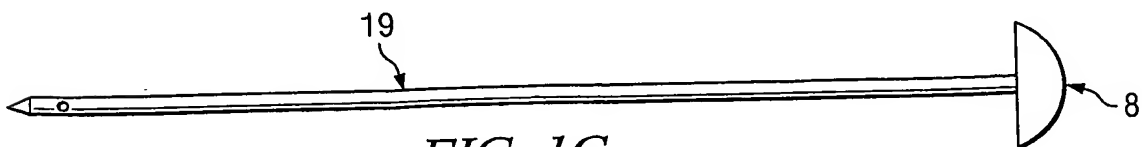


FIG. 1C

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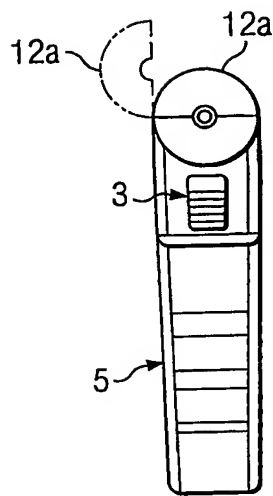


FIG. 1D

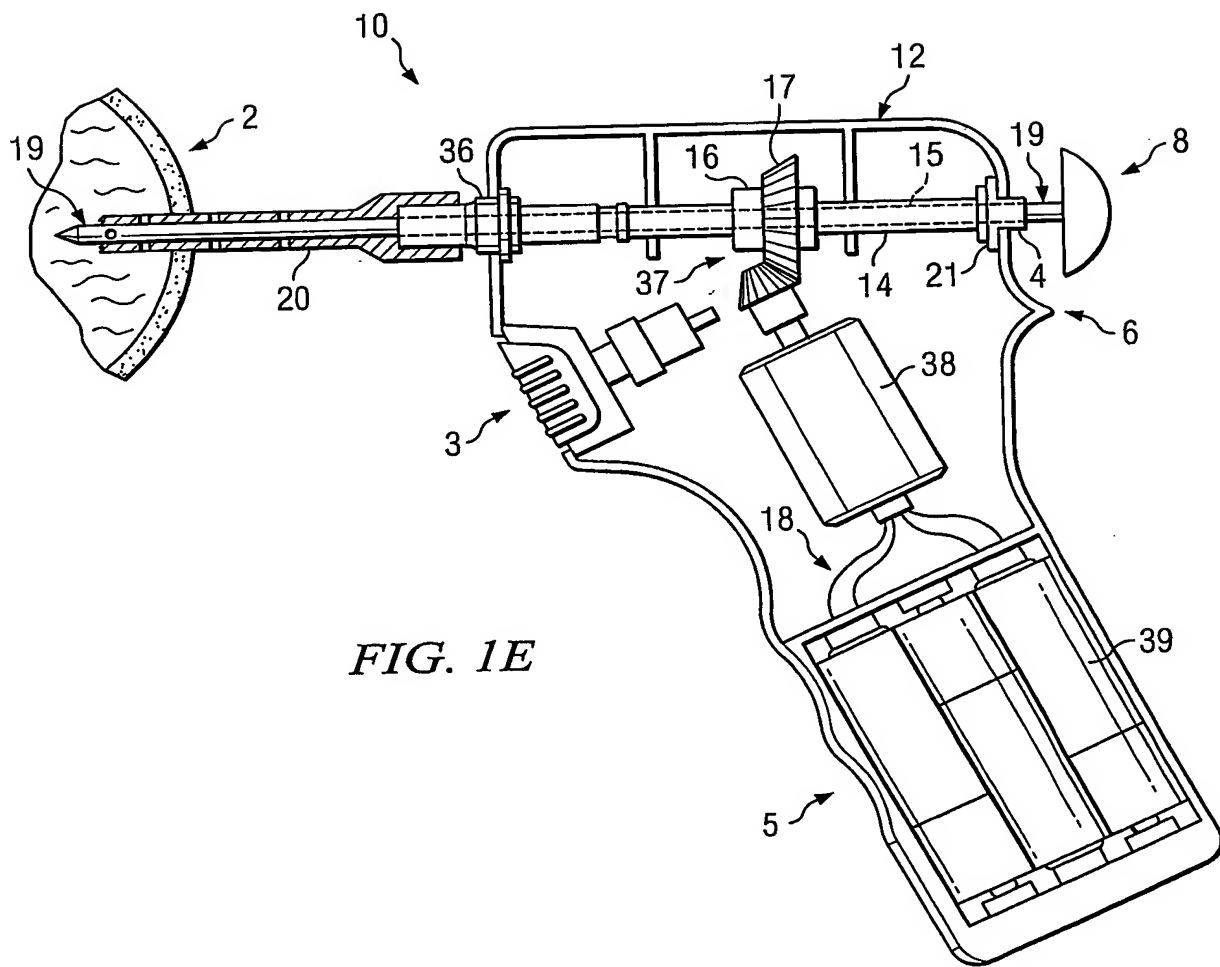


FIG. 1E

3/6

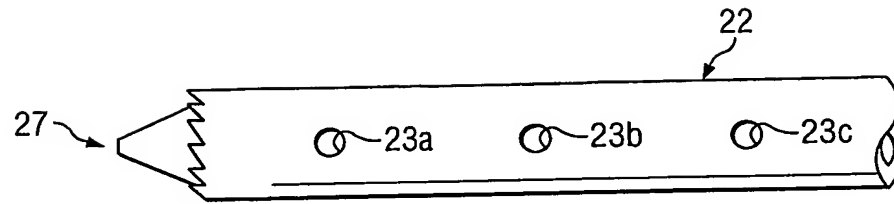


FIG. 2A

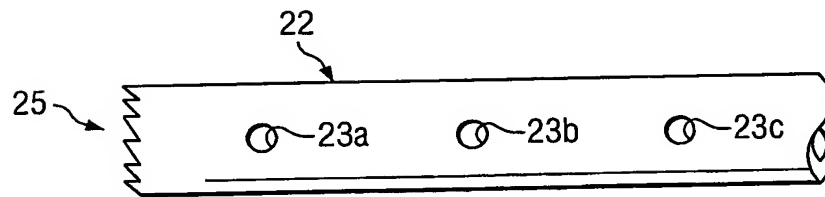


FIG. 2B

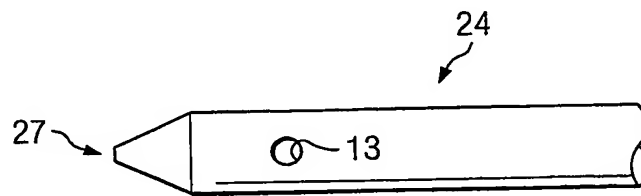


FIG. 2C

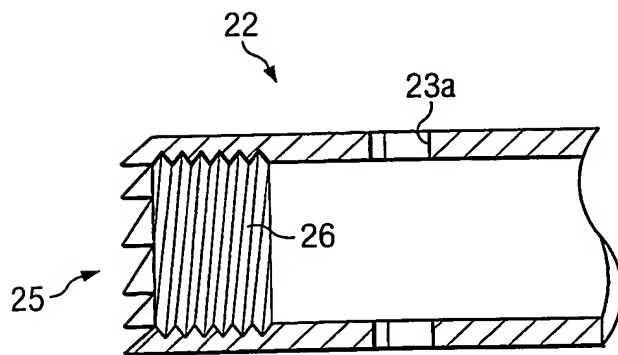


FIG. 2D

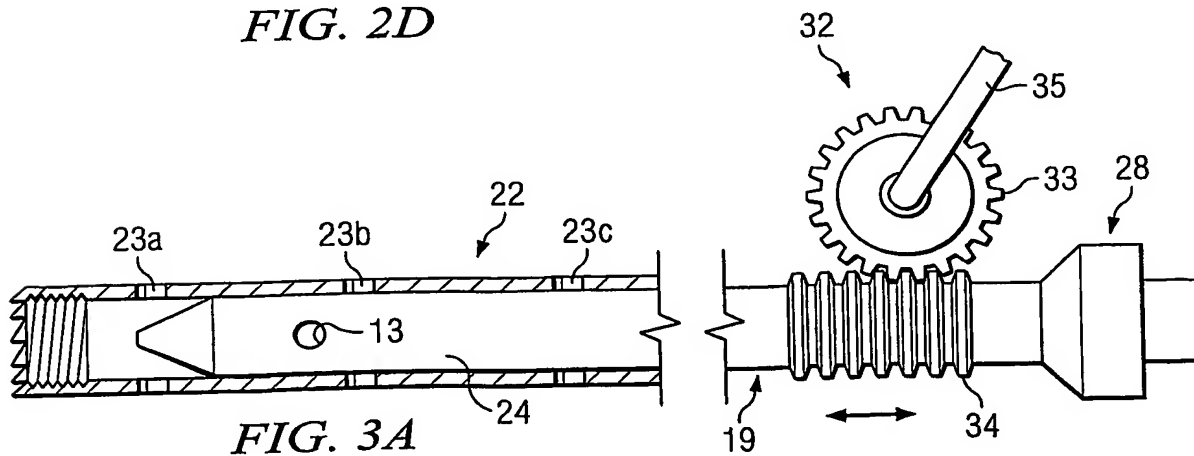
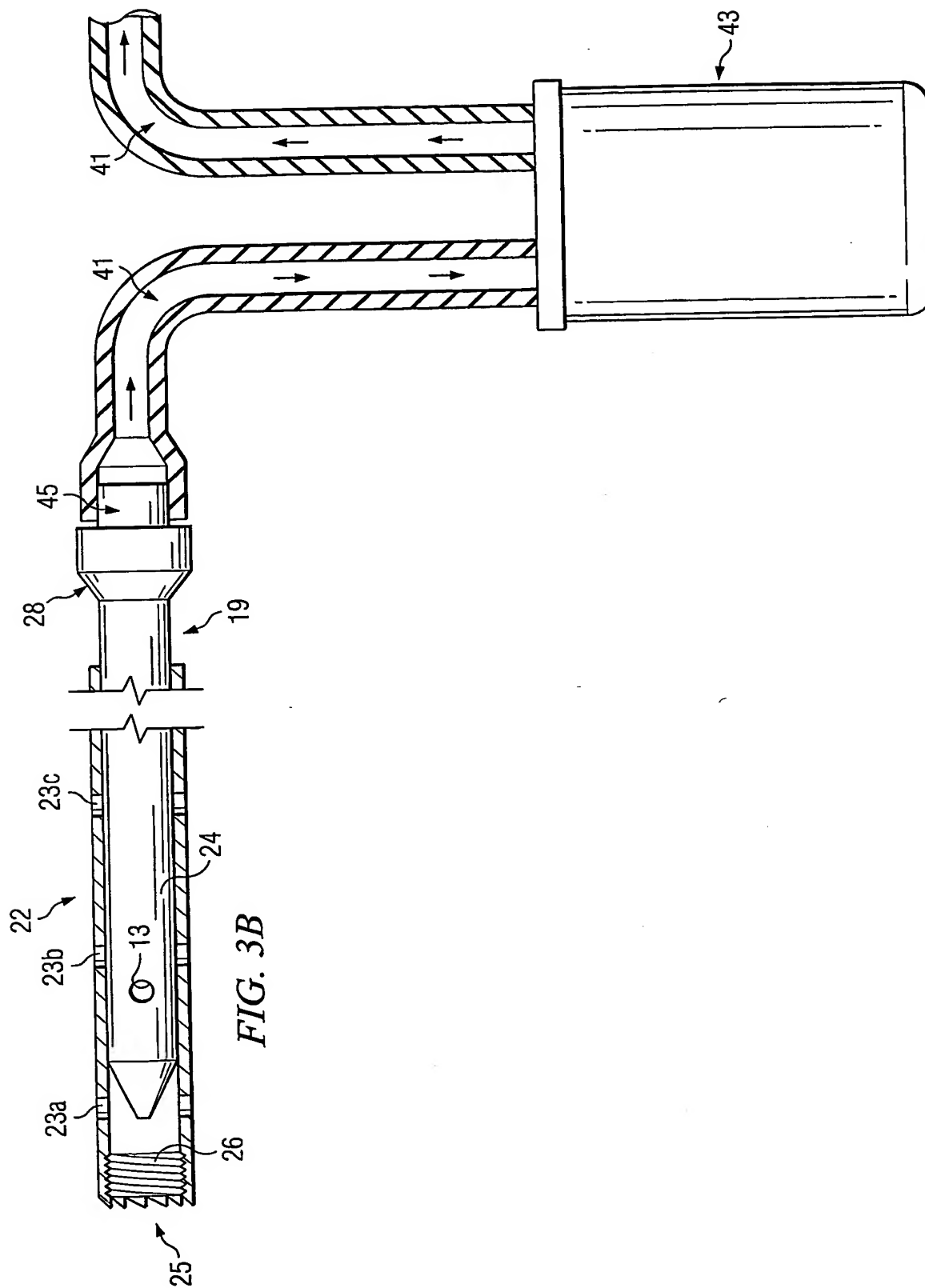


FIG. 3A



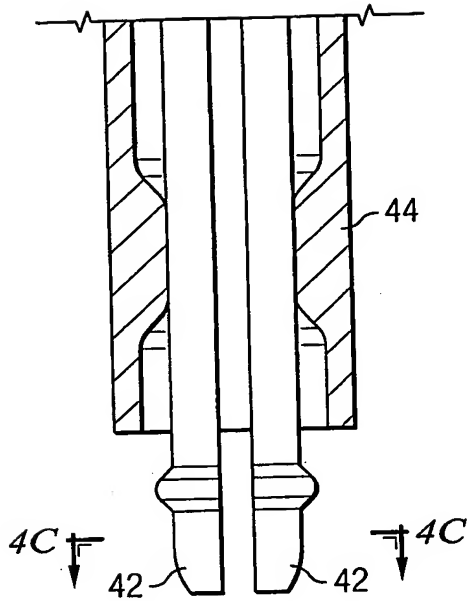


FIG. 4A

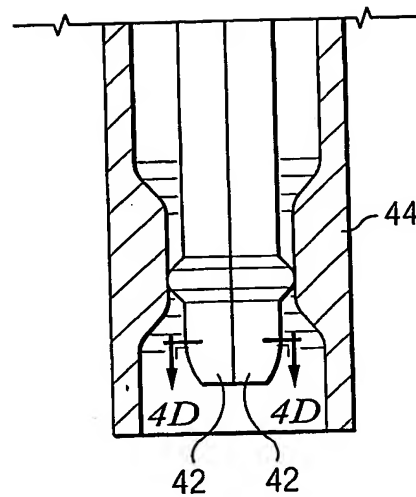


FIG. 4B

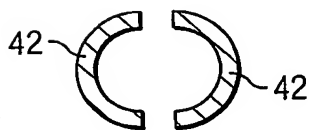


FIG. 4C

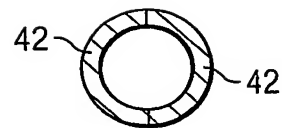


FIG. 4D

6/6

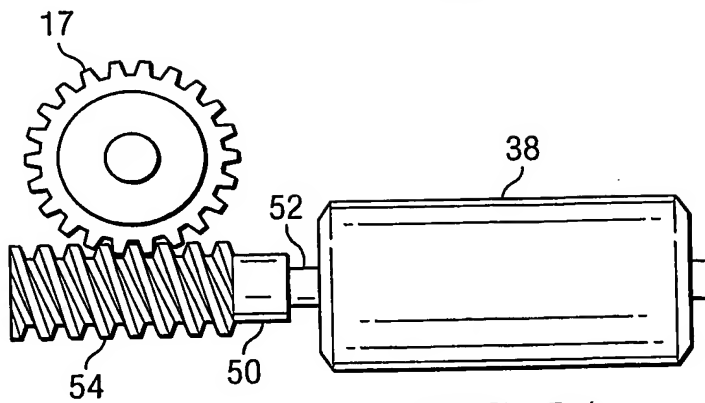


FIG. 5A

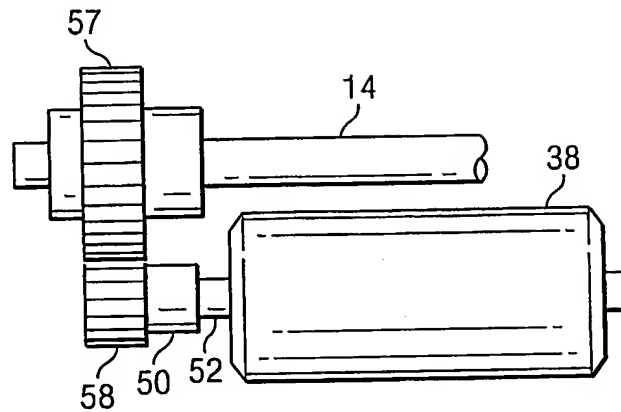


FIG. 5B

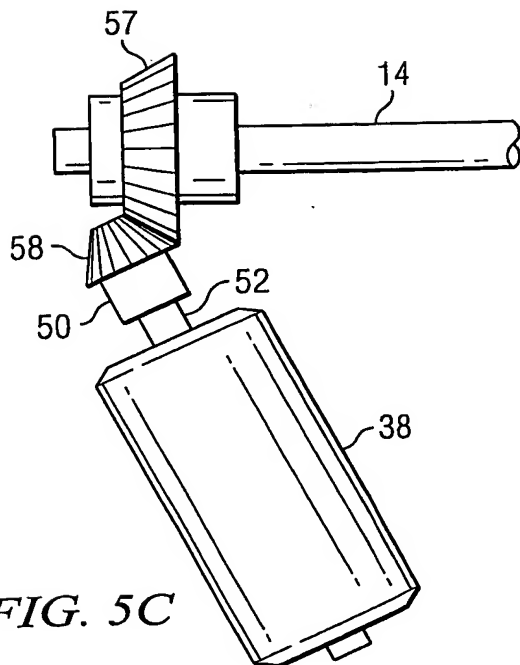


FIG. 5C

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 06337 A (CYBERDENT, INC.) 19 February 1998 (1998-02-19) abstract; figures page 7, line 9 -page 11, line 28	1-7, 10, 14, 28
Y	---	16, 18, 19, 23, 27
Y	FR 853 349 A (NEUMANN) 15 March 1940 (1940-03-15) the whole document	16, 18, 19, 23, 27
A	GB 2 130 890 A (DOWNS SURGICAL PLC) 13 June 1984 (1984-06-13) the whole document	1, 3, 4, 6, 12, 14, 16, 18, 19, 25, 27, 28, 30, 31

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Z document member of the same patent family

Date of the actual completion of the international search

8 September 2003

Date of mailing of the international search report

16/09/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Burgos, R

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	EP 0 807 412 A (UNITED STATES SURGICAL CORPORATION) 19 November 1997 (1997-11-19) figures ---	
A	WO 96 31164 A (GIBBS) 10 October 1996 (1996-10-10) abstract; figures -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/17167

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 33-36
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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